CPMA®
COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

March 13, 2013

By Air Mail and Email

Ms. Erika Uchino
Deputy Director, Chemical Safety Office
Chemical Management Policy Division
Manufacturing Industries Bureau
Ministry of Economy, Trade and Industry
131 Kasumigaseki, Chiyoda-ku
Tokyo 100-8901
Japan

Re: Regulation of Monochlorinated, Dichlorinated and Polychlorinated Biphenyls in the United States and Canada

Dear Ms. Uchino:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") to provide you with information on the regulation of monochlorinated, dichlorinated and polychlorinated biphenyls (collectively, "PCB's") in the United States and Canada.

CPMA is an industry trade association representing color pigments companies in Canada, Mexico and the United States. CPMA represents small, medium and large color pigments manufacturers throughout Canada, Mexico and United States, accounting for the bulk of the production of pigments in North America. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers and ceramics. Color pigments manufacturers located in other countries with sales in Canada, Mexico and the United States, and suppliers of intermediates to the pigments industry are also members of the Association.

300 North Washington Street, Suite 105 • Alexandria, Virginia 22314 • USA
Phone: (703) 684-4044 • Fax: (703) 684-1795 • e-mail: cpma@cpma.com

Dr. Walther Hofherr, Executive Director of the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers ("ETAD"), contacted CPMA to inform us that you are seeking information on the regulation in the United States and Canada of PCB's, including the use of factors for reporting monochlorinated and dichlorinated biphenyls. CPMA and ETAD maintain a close working relationship and have agreed that CPMA is in the best position to respond to this inquiry, since it pertains to the pigments industry in the United States and Canada.

The following letter will discuss the regulatory approach in each jurisdiction, the United States and Canada, limiting the manufacture, processing, distribution and use of PCB's. It should be noted that, in the United States, the use of the term PCB's in regulations addresses combinations of chlorinated biphenyls, including monochlorinated and dichlorinated biphenyls. The use of the term PCB's in regulations in Canada and many other jurisdictions addresses only compounds with more than two chlorine atoms.

The United States regulations address all 209 congeners of PCB's and have a separate rule for inadvertent generation of PCB's, which provides specific provisions for monochlorinated and dichlorinated biphenyls. The Canadian regulations have a general rule for PCB's, which are defined differently from the definition used in the United States, and include a specific exception to the general rule, which exception addresses pigments. While the regulations in the two countries differ, in that the United States has specific provisions for discounting monochlorinated and dichlorinated biphenyls when calculating PCB's, their effect is similar.

UNITED STATES REGULATIONS

In 1976, the United States passed the Toxic Substances Control Act (the "TSCA")(15 United States Code ("U.S.C.") § 2601-2692), which authorizes the Environmental Protection Agency ("EPA") to secure information on all new and existing chemical substances, including PCB's, as well as to control any of the substances that were determined to cause unreasonable risk to public health or the environment. The TSCA provides that:

> "(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.
>
> (B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(e).

In the United States, pursuant to the TSCA regulations, PCB's are defined as:

> "…any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees or any combination of substances which contains such substance." 40 Code of Federal Regulations ("C.F.R.") § 761.3.

In 1984, a final rule was passed amending the regulations on the manufacturing, processing, distributing, and use of PCB's (the "Rule") pursuant to the TSCA. 40 C.F.R. § 761. Generally, the addition of PCB's to any product in the United States is banned unless an exemption is granted by the EPA under the regulations. 15 U.S.C. § 2605(e). One such exemption was established for certain inadvertently generated PCB's. 40 C.F.R. § 761.1(f).

The Rule sets permissible limits for inadvertently generated PCB's in products, air emissions, water discharges and waste disposal, based on EPA's determination that inadvertent PCB's generated in these processes at prescribed levels do not present an unreasonable risk of injury to health or the environment. 40 C.F.R. § 761. For purposes of compliance with

other environmental statutes and regulations in the United States, including the Clean Water Act, all chlorinated biphenyls are included in the definition of PCB's. Consequently, under these other statutes, no distinction is made regarding monochlorinated and dichlorinated biphenyls.

Under the Rule, inadvertently generated concentrations of PCB's present in all products, except detergent bars, are regulated under the excluded products and processes section of the Rule. 40 C.F.R. § 761.3.

Excluded PCB products are defined as:

> "PCB materials which appear at concentrations less than 50 ppm ("parts per million"), including but not limited to:
>
> (1) Non-Aroclor[1] inadvertently generated PCB's as a byproduct or impurity resulting from a chemical manufacturing process." 40 C.F.R. § 761.3.

When calculating inadvertently generated PCB's in products and processes regulated under the TSCA, the EPA determined that inadvertently generated monochlorinated and dichlorinated biphenyls should be discounted, because they are less harmful than the more highly chlorinated biphenyls. 49 Federal Register ("Fed. Reg.") 28176. Please take note that all documents referenced in this letter are available for free online except for the 1984 Federal Register (49 Fed. Reg. 28176), which is only available for purchase. Because it may prove difficult to obtain, I have included a copy of the 1984 Federal Register for your convenience.

When adopting the Rule, the EPA found that:

> "[The] quantitation of inadvertently generated PCBs to meet the criteria...is to be calculated after discounting the concentration of

[1] Aroclor is a registered trademark for a group of polychlorinated biphenyls that were manufactured by the Monsanto Company prior to 1976 (U.S. Environmental Protection Agency. *Aroclor and Other PCB Mixtures.* ONLINE. 2013. Available: http://www.epa.gov/osw/hazard/tsd/pcbs/pubs/aroclor.htm.).

> monochlorinated biphenyls by a factor of 50 and dichlorinated biphenyls by a factor of 5. These discounting factors do not apply to recycled PCBs." 49 Fed. Reg. 28176. See also 40 C.F.R. § 761.3.

The EPA provided detail on their reasoning in the preamble to the Rule, which states:

> "...the consensus proposal provided discounting factors for monochlorinated biphenyls and dichlorinated biphenyls of 50 and 5, respectively...The consensus proposal attributes these monitoring results to several factors that distinguish between monochlorinated and dichlorinated biphenyls and the higher chlorinated biphenyls.
>
> In contrast to the more highly chlorinated biphenyls, the monochlorinated and dichlorinated biphenyls are: (1) Less likely to adsorb to solids; (2) more likely to dissolve in water; (3) more likely to move from natural bodies of water to air; (4) more likely to biodegrade; and (5) less likely to bioaccumulate. Thus, CMA [Chemical Manufacturers Association], EDF [Environmental Defense Fund], and NRDC [National Resources Defense Council] concluded that monochlorinated and dichlorinated biphenyls are less persistent in the environment and less likely to magnify or accumulate than the more highly chlorinated biphenyls.
>
> In support of these discounting factors, CMA, EDF, and NRDC considered data...to amend 40 CFR Part 761. In general, this information demonstrates that monochlorinated and dichlorinated biphenyls are less persistent than more highly chlorinated biphenyls. The information included environmental variables such as environmental persistence, residence time in water, and fish bioconcentration. Adipose and plasma levels in capacitor workers

and levels in human milk samples were also considered. A chart is presented in the consensus proposal that compares persistence data for monochlorinated and dichlorinated biphenyls with persistence data for trichlorinated biphenyls, demonstrating that monochlorinated and dichlorinated biphenyls are less persistent than trichlorinated biphenyls.

These discounting factors encompass all activities involving inadvertently generated monochlorinated and dichlorinated PCBs, but do not apply to any other PCBs subject to EPA regulation. This position is consistent with previous EPA PCB regulatory policy. The Agency has a long history, in regulations under both the Clean Water Act and TSCA, of covering the lesser chlorinated PCBs in the same manner as the higher chlorinated PCBs. The decision to affect this policy under Clean Water Act regulations was upheld by the United States Court of Appeals of the District of Columbia Circuit in EDF v. EPA, 598 F.2d 62 (1978). EPA has continued this policy under TSCA regulations. The definition of PCBs under 40 CFR 761.3 states that PCBs consist of any chemical substance "that is limited to the biphenyl molecule that has been chlorinated to varying degrees.

Today's rule is making a small exception to this long-standing policy. While EPA is continuing to regulate the lesser chlorinated PCBs for all intentionally generated PCBs, the Agency has determined that discounting inadvertently generated monochlorinated and dichlorinated bipheyls will not present an unreasonable risk. EPA has arrived at this decision based on the very small amounts of monochlorinated and dichlorinated biphenyls that will be generated and released as a result of this rule, the fact that these PCB homologs are generally less persistent and less likely to

> bioaccumulate than the higher chlorinated PCB homologs and the high cost of preventing the generation of the monochlorinated and dichlorinated biphenyls in manufacturing processes. Accordingly, EPA has determined that the incremental risk reduction that would result from more stringent regulation of the monochlorinated and dichlorinated biphenyls in the limited circumstances of this regulation is outweighed by the costs that would be incurred." 49 Fed. Reg. 28179.

In addition to the provision for excluded products, the Rule has a provision for excluded manufacturing processes. 40 C.F.R. § 761.3. Excluded manufacturing processes are described as follows:

> "(1) The concentration of inadvertently generated PCBs in products leaving any manufacturing site or imported into the United States must have an annual average of less than 25 ppm, with a 50 ppm maximum.
>
> (2) The concentration of inadvertently generated PCBs in the components of detergent bars leaving the manufacturing site or imported into the United States must be less than 5 ppm.
>
> (3) The release of inadvertently generated PCBs at the point at which emissions are vented to ambient air must be less than 10 ppm.
>
> (4) The amount of inadvertently generated PCBs added to water discharged from a manufacturing site must be less than 100 micrograms per resolvable gas chromatographic peak per liter of water discharged.
>
> (5) Disposal of any other process wastes above concentrations of 50 ppm PCB must be in accordance with subpart D of this part." 40 C.F.R. § 761.3.

In addition to meeting the definitional requirements for the excluded products and processes exemption, EPA requires that a certification be filed by manufacturers in order to maintain the exemption. 40 C.F.R. § 761.185. The regulations provide extensive detail on the requirements of the certification. That is as follows:

> "(a) In addition to meeting the basic requirements of § 761.1(f) and the definition of excluded manufacturing processes at § 761.3, manufacturers with processes inadvertently generating PCBs and importers of products containing inadvertently generated PCBs must report to EPA any excluded manufacturing process or imports for which the concentration of PCBs in products leaving the manufacturing site or imported is greater than 2 micrograms per gram (2 µg/g, roughly 2 ppm) for any resolvable gas chromatographic peak. Such reports must be filed by October 1, 1984 or, if no processes or imports require reports at the time, within 90 days of having processes or imports for which such reports are required.
>
> (b) Manufacturers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the number, the type, and the location of excluded manufacturing processes in which PCBs are generated when the PCB level in products leaving any manufacturing site is greater than 2 µg/g for any resolvable gas chromatographic peak. Importers required to report by paragraph (a) of this section must transmit a letter notifying EPA of the concentration of PCBs in imported products when the PCB concentration of products being imported is greater than 2 µg/g for any resolvable gas chromatographic peak. Persons must also certify the following:

(1) Their compliance with all applicable requirements of § 761.1(f), including any applicable requirements for air and water releases and process waste disposal.

(2) Whether determinations of compliance are based on actual monitoring of PCB levels or on theoretical assessments.

(3) That such determinations of compliance are being maintained.

(4) If the determination of compliance is based on a theoretical assessment, the letter must also notify EPA of the estimated PCB concentration levels generated and released.

(c) Any person who reports pursuant to paragraph (a) of this section:

(1) Must have performed either a theoretical analysis or actual monitoring of PCB concentrations.

(2) Must maintain for a period of three years after ceasing process operations or importation, or for seven years, whichever is shorter, records containing the following information:

(i) *Theoretical analysis.* Manufacturers records must include: the reaction or reactions believed to be generating PCBs; the levels of PCBs generated; and the levels of PCBs released. Importers records must include: the reaction or reactions believed to be generating PCBs and the levels of PCBs generated; the basis for all estimations of PCB concentrations; and the name and

qualifications of the person or persons performing the theoretical analysis; or

(ii) *Actual monitoring.*
(A) The method of analysis.
(B) The results of the analysis, including data from the Quality Assurance Plan.
(C) Description of the sample matrix.
(D) The name of the analyst or analysts.
(E) The date and time of the analysis.
(F) Numbers for the lots from which the samples are taken.

(d) The certification required by paragraph (b) of this section must be signed by a responsible corporate officer. This certification must be maintained by each facility or importer for a period of three years after ceasing process operation or importation, or for seven years, whichever is shorter, and must be made available to EPA upon request. For the purpose of this section, a responsible corporate officer means:

(1) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation.

(2) The manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $25,000,000 (in second quarter 1980 dollars), if

authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(e) Any person signing a document under paragraph (d) of this section shall also make the following certification: I CERTIFY UNDER PENALTY OF LAW THAT THIS DOCUMENT AND ALL ATTACHMENTS WERE PREPARED UNDER MY DIRECTION OR SUPERVISION IN ACCORDANCE WITH A SYSTEM DESIGNED TO ASSURE THAT QUALIFIED PERSONNEL PROPERLY GATHER AND EVALUATE INFORMATION. BASED ON MY INQUIRY OF THE PERSON OR PERSONS DIRECTLY RESPONSIBLE FOR GATHERING INFORMATION, THE INFORMATION IS, TO THE BEST OF MY KNOWLEDGE AND BELIEF, TRUE, ACCURATE, AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT PENALTIES FOR FALSIFYING INFORMATION, INCLUDING THE POSSIBILITY OF FINES AND IMPRISONMENT FOR KNOWING VIOLATIONS.DATED:SIGNATURE:

(f) This report must be submitted to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: PCB Notification. This report must be submitted by October 1, 1984 or within 90 days of starting up processes or commencing importation of PCBs.

(g) This certification process must be repeated whenever process conditions are significantly modified to make the previous certification no longer valid." 40 C.F.R. § 761.185.

CANADIAN REGULATIONS

In 1999, the Federal government of Canada enacted a new Canadian Environmental Protection Act ("CEPA")(S.C. ("Statutes of Canada") 1999, c. 33) in an attempt to prevent pollution and

protect the environment and human health by regulating and managing toxic substances, including PCB's. In 2008, Canada amended the regulations on PCB's adopted pursuant to the CEPA by permitting some activities that incidentally produce a small concentration of PCB's (the "Regulation"). SOR ("Statutory Orders and Regulations")/2008-273(Can.).

Generally, the Regulation defines PCB's as any chlorobiphenyl with more than two chlorines. S.C. 1999, c. 33, Sch. 1. The Canadian regulations differ from the United States regulations in that Canada does not define PCB's to include monochlorinated and dichlorinated biphenyls. Because monochlorinated and dichlorinated biphenyls are not included in the definition of PCB's, they are not regulated as PCB's in Canada.

The Regulation has a general prohibition on releasing PCB's into the environment and a specific exception to the general rules for "colouring pigments". SOR/2008-273. The general prohibition provision in the Regulation provides that:

> "5. (1) No person shall release PCBs into the environment, other than from the equipment referred to in subsection (2), in a concentration of
>
> (*a*) 2 mg/kg or more for a liquid containing PCBs; or
>
> (*b*) 50 mg/kg or more for a solid containing PCBs.
>
> (2) No person shall release more than one gram of PCBs into the environment from equipment referred to in section 16 that is in use or from equipment in use for which an extension has been granted under section 17.
>
> 6. Except as provided in these Regulations, no person shall
>
> (*a*) manufacture, export or import PCBs or a

> product containing PCBs in a concentration of 2 mg/kg or more;
>
> (*b*) offer for sale or sell PCBs or a product containing PCBs in a concentration of 50 mg/kg or more; or
>
> (*c*) process or use PCBs or a product containing PCBs." SOR/2008-273, s.2.

Following the general prohibition provision on releasing PCB's into the environment, the Regulation lists specifically permitted activities, which include the provision for colouring pigments. This provision of the Regulation provides that:

> "…(1) A person may manufacture, export, import, offer for sale, sell, process and use a colouring pigment containing PCBs produced incidentally if the concentration of the PCBs is less than 50 mg/kg.
>
> (2) Despite subsection (1), the annual average concentration of PCB's produced incidentally in colouring pigments that a person may manufacture, export, import, offer for sale, sell, process and use shall not exceed 25 mg/kg." SOR/2008-273, s.2.

Colouring pigments are the only specific exclusion granted under the Regulation for incidentally present PCB's, and the provision allowing the sale of colouring pigments with concentrations of PCB's below 50 ppm is not extended to other products or processes in Canada. Incidentally generated PCBs in colouring pigments which are dispersed in liquids, such as inks, paints and plastics, are excluded from the general prohibition on PCBs above 2mg/kg in a liquid.

In addition to meeting these requirements, annual reporting is required of manufacturers, exporters and importers of pigments containing PCB's, with reports due on December 31st of each calendar year. SOR/2008-273 s.4. The Regulation requires specific detail in the annual report and provides an explanation of the requirements of the annual report, as follows:

"The person who manufactures, exports or imports colouring pigment in accordance with section 11 shall prepare a report that is current to December 31 in each calendar year in which the person manufactures, imports or exports the colouring pigment and that contains the following information:

(a) the name, civic and mailing addresses, telephone number, fax number, if any, and e-mail address, if any, of the person and of any person authorized to act on that person's behalf;

(b) an indication of whether the person manufactures, exports or imports colouring pigment;

(c) the quantity of colouring pigment, expressed in kilograms, the maximum concentration of PCBs in the colouring pigment, expressed in mg/kg, and the average annual concentration of PCBs in the colouring pigment, expressed in mg/kg, that is manufactured, imported or exported in that calendar year;

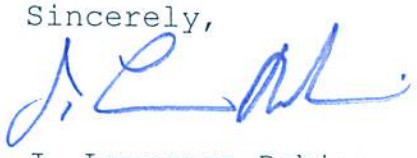
(d) in the case of importing, the name, telephone number and civic and mailing addresses of the person from whom the colouring pigment is imported and, in the case of exporting, the name, telephone number and civic and mailing addresses of the person to whom the colouring pigment is exported; and

(e) a certification that the information is accurate and complete and that is dated and signed by the person or by a person authorized to act on their behalf." SOR/2008-273 s.4.

CLOSING

CPMA is pleased to provide you with this information on the regulatory approach to PCB's in the United States and in Canada. If you have any questions regarding the detail in this letter or any other matter related to the color pigments market in North America, please feel free to contact CPMA.

Sincerely,



J. Lawrence Robinson
President

cc: Dr. Walther Hofherr, Executive Director, ETAD (by email)